



United States Department of Agriculture

Food Safety and  
Inspection Service

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Mr. Greg Read, First Assistant Secretary  
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Australian Government Department of Agriculture, Fisheries and  
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SEP 09 2014

Dear Mr. Read,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Australia's meat inspection system from July 29 through August 21, 2013. FSIS received your comments to the report, and has included them as an attachment to the enclosed copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-0676, or electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov).

Sincerely,

Dr. Shaukat H. Syed  
Director  
International Audit Staff  
Office of Investigation, Enforcement and Audit

Enclosure

**AUSTRALIA**  
**FINAL AUDIT REPORT**

September 9, 2014  
Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

This report describes the outcome of an ongoing equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from July 29 – August 21, 2013, to determine whether Australia's food safety system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products that are unadulterated, safe, wholesome, and properly labeled. Australia is eligible to export meat and poultry products (ratites only) to the United States.

The audit was designed to verify equivalence of Australia's meat and poultry inspection system and focused on the six main system components: (1) Government Oversight; (2) Statutory Authority and Food Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. FSIS reviewed information provided by the Central Competent Authority (CCA) in FSIS' self-reporting tool (SRT), reports of corrective actions instituted by the CCA to address 2011 FSIS audit findings, and reports of corrective actions implemented to address point of entry (POE) violations reported by FSIS from 2011 to September 2013. FSIS also verified the implementation of the post-mortem inspection procedures introduced by Australia within its meat inspection system<sup>1</sup>.

The on-site audit included visits to CCA headquarters office, six local inspection offices, six livestock slaughter facilities identified as repeat POE violators, and two private microbiological laboratories. The on-site audit findings are summarized below and are further addressed in the body of this report.

- The CCA instructions to in-plant inspection personnel omitted provisions that would instruct inspectors to document deviations from the critical control point for zero tolerance contamination (CCP-ZT) as evidence of inadequate implementation of establishments' HACCP plans. Official data show frequent CCP-ZT deviations, but the CCA does not use that information to assess the adequacy of establishments' HACCP plans.
- The CCA has not adequately verified that establishments' HACCP plans include monitoring the CCPs at an appropriate frequency, adequately identifying the root causes of CCP deviations, and instituting corrective actions that prevent their recurrence. Furthermore, the CCA has not verified that establishments that have adopted the alternate post-mortem inspection system have adequately reassessed their HACCP plans.
- In-plant officials have not critically assessed establishments' sanitation programs, their implementation, or required abatement of potential sources of product contamination. Monitoring of sanitary conditions of equipment within establishments is also inadequate.

The audit results indicate that Australia's food safety inspection system continues to maintain equivalence with the United States system and is operating at an "adequate" level of performance. The CCA meets the core criteria for all six equivalence components. However, the reported findings for the HACCP component make evident inadequacies in the implementation of HACCP systems. Specifically, the CCP for ZT included in the HACCP plans of slaughter establishments does not work as designed to control ZT contamination. Furthermore, the CCA verification efforts are inadequate to effectively ensure that slaughter establishments control ZT contamination. In addition, FSIS POE records show that in the latter portion of calendar year 2013 and the first part of 2014, beef products shipped to the United States from Australian meat establishments continue to be involved in violations of United States food safety standards related to ZT violations. During the exit meeting, the CCA noted that it had initiated immediate and long-term actions to address the above audit observations. FSIS expects that the CCA will implement prompt corrective actions to address the above reported findings and provide to FSIS a report on the adequacy of their implementation within the next sixty days.

The CCA provided comments addressing the findings presented in this report. The comments are found in Appendix B.

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<sup>1</sup> Australia's Meat Safety Enhancement Program; Notice of affirmation of Equivalence Decision <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2009-0020.htm>

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an ongoing equivalence verification of Australia's meat inspection system that included an on-site audit of the performance of the system that took place from July 29 through August 21, 2013.

Australia is eligible to export meat and poultry products to the United States; however, meat products comprise the majority of such exports. During fiscal year 2013, Australia shipped to the United States 619,531,670 lbs. of raw meat products including beef, goat, lamb, and mutton. From that amount, 287,759 lbs. were refused entry at FSIS' point of entry (POE) due to food safety violations related to zero tolerance (ZT) (fecal, ingesta and milk contamination) and *Escherichia coli* O157:H7 (*E. coli* O157:H7). In fiscal year 2012, FSIS refused entry to 192,007 lbs. of similar meat products involved in the same types of POE violations. FSIS focused the on-site audit on the meat inspection portion of the Australian food safety system.

The audit standards applied to evaluate the meat inspection system of Australia (MISA) included applicable legislation determined by FSIS to be equivalent as part of the initial equivalence process, as well as any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement. This audit was conducted pursuant to the specific provisions of the United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906)
- The Food Safety and Inspection Service Regulations (9 CFR, Chapter III, Part 327)

## II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Australia's food safety system governing meat production continues to be equivalent to that of the United States, with the ability to produce and export products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six components of the program to determine if they are equivalent and can maintain the system's equivalence. The six equivalence components are the following: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Program; and (6) Microbiological Testing Programs. FSIS also verified the adequacy of implementation of the newly introduced post mortem inspection procedures within the MISA; and the corrective measures implemented by the Central Competent Authority (CCA) to address the finding of the 2011 FSIS audit and recurrence of point of entry (POE) violations.

## III. AUDIT METHODOLOGY

For this equivalence verification audit, FSIS utilized its established four-phase process: planning, execution (on-site), evaluation, and feedback. Each phase is described below.

The first phase involved document and data analysis of previous audit findings and corrective actions. The FSIS auditor examined the six equivalence components of the MISA, FSIS data on exported product types and volumes from Australia as well as POE testing results, and other data collected by

FSIS since the last on-site audit. The FSIS auditor also reviewed documents that describe the design of AEMIS, which, as indicated by CCA officials, includes the inspection methods and procedures currently in place at establishments certified to produce meat products for the United States market, and those in place at establishments that produce meat products for other markets. Furthermore, FSIS assessed the corrective actions proffered by the CCA to address the findings of the 2011 audit. The auditor also examined reports provided by the CCA on the verification of corrective actions that the sectors of the MISA implemented between the 2011 audit and October 2013 to address POE violations reported by FSIS.

The analysis of available information served as the basis to plan the on-site audit itinerary that included visits to the CCA headquarters office, six local inspection offices, and six out of 79 establishments currently certified to export meat and poultry products to the United States. The six selected establishments included two ovine, two caprine, and two bovine slaughter/fabrication facilities, whose raw meat products repeatedly failed to meet FSIS food safety standards during re-inspection at United States' POE. The audit also included on-site audits of two private microbiological laboratories that analyze product samples from the audited establishments. Laboratories that conduct chemical residue analysis were not included in the on-site audit but their functions were assessed by reviewing records and other documents presented by the CCA before and during the on-site audit. Additional information reviewed by the FSIS auditor included the responses provided by the CCA via the self-reporting tool (SRT), outlining the current structure of the inspection system, and identifying significant changes, which have occurred since the last FSIS audit.

The second phase was the on-site verification. FSIS verified the CCA's oversight activities through on-site document reviews, interviews, observations, and site visits. The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters and at the six inspection offices located at the audited establishments. FSIS also verified that the national system of inspection, verification, and enforcement was being implemented in accordance with equivalent Australian statute and regulations. This ongoing equivalence verification audit also assessed the corrective measures implemented by the CCA to address the findings of the 2011 audit and the POE violations reported by FSIS. Additionally, FSIS assessed the adequacy of the CCA's oversight of its technical support by reviewing pertinent documentation related to the functions of the chemical residue laboratories of the system and by evaluating the technical and administrative controls maintained at two private microbiological laboratories of the system.

During the on-site visits, FSIS paid particular attention to the extent to which the sectors of the MISA-government offices, establishments, and laboratories- interact at different levels to control hazards and prevent non-compliances that threaten food safety. The review placed a particular emphasis on the CCA's ability to provide oversight through supervisory reviews, which ensure that the meat inspection system continues to operate in accordance with the regulations of the government of Australia and fulfill eligibility requirements specified in United States Code of Federal Regulations Title 9, Section 327.2.

The third phase of the audit is evaluation. FSIS conducted evaluation activities throughout the entire audit process. Prior to, and during, the on-site verification and upon return to the United States, the FSIS auditor determined whether or not the CCA's performance was consistent with the information provided to FSIS and supported a finding that the performance of the MISA was equivalent to the

United States' meat inspection system. The results of the evaluation are discussed in the corresponding sections of this report for each of the system's components.

The final phase of the audit process is feedback, which begins with FSIS providing a draft audit report to the CCA and giving them an opportunity for comment. After reviewing the CCA comments and responses to all findings, FSIS finalizes the report. The CCA develops an action plan to address any issues raised by the audit, and FSIS monitors resolution of all issues.

#### **IV. COMPONENT ONE: GOVERNMENT OVERSIGHT**

The first of the six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import eligibility requirements state that a foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the U.S. system of meat inspection. Accordingly, FSIS evaluated this component by conducting a review and analysis of documentation submitted by the CCA as support for the responses provided in the SRT, as well as on-site record reviews, interviews, and observations made by the FSIS auditor at government offices, establishments, and laboratories of the system.

FSIS assessed the organization and administration of the MISA and confirmed that the Food Division of Australia's Department of Agriculture, Fisheries and Forestry (DAFF) continues to serve as the CCA responsible for the full spectrum of production of safe food for domestic consumption and for export. Additionally, the Food Division (FD) is headed by a First Assistant Secretary who oversees the functions of three Assistant Secretaries in charge of developing and maintaining export standards, ensuring food safety, and managing food exports. The Assistant Secretary for Food Exports manages delivery of regulatory oversight of the MISA with the assistance of three Field Operations Managers (FOMs), who supervise the Area Technical Managers (ATMs), and the government officials stationed at the establishments, i.e., On Plant Veterinarians (OPV) and Food Safety Meat Assessors (FSMA). At the in-plant level, the OPVs in turn, supervise the FSMAs and verify the performance of the Australian Government authorized officers (AAOs), who are non-government officials, but trained inspectors authorized by the Australian government to conduct post-mortem inspection duties at certified establishments.

FSIS reviewed documents provided by the CCA that describe the protocol followed by meat producing establishments to obtain approval and certification to export meat products to the United States. The information provided shows that eligible establishments must first register with the CCA, maintain consistent regulatory compliance, and be free from debt to the commonwealth. In addition, establishments file an application for certification with the FD and develop an Approved Arrangement (AA). An AA is described as a series of documents evaluated and approved by CCA officials that describe the processes and practices establishments follow to implement quality systems and food safety program, and to meet regulatory and certification requirements. The FSIS auditor verified that the CCA has added a Non-Interference Clause (NIC) for AAOs to the list of required components of the AAs. In accordance with the NIC, AAOs specifically assigned to perform post-mortem inspection duties on behalf of the Australian Government must be supported in their functions by establishments' staff, and the establishments must not interfere with the performance of their post-mortem inspection duties.

As part of the mandated requirements for establishments certified to export to the United States, the AAs of such establishments must include a HACCP program that establishes a CCP to ensure that there is

zero tolerance for visible fecal, ingesta, or milk material on carcasses (ZT), as required by the CCA. The CCA also requires that establishments and in-plant government officials conduct visual Meat Hygiene Assessments (MHA) to verify the adequacy of hygienic conditions of meat products prior to shipping and to determine the Product Hygiene Index (PHI) for the establishments. Results of the MHA conducted by in-plant OPVs and FSMAs, and establishment personnel, are compiled and submitted to a centrally located data processing site on a monthly basis. The data from all certified establishments is analyzed and packaged as a nationwide comparative analysis of the PHI standing of each establishment, which is sent by the CCA to establishments and in-plant government officials. As indicated by CCA officials, this monitoring mechanism permits the MISA to rapidly detect issues as developing trends that are corrected early to maintain market access. In addition, the CCA describes in its Meat Hygiene Assessment Objective Methods for the Monitoring of Processes and Product, 2<sup>nd</sup> edition, that MHAs are additional activities that will assist in the implementation of HACCP plans. FSIS assessed this feature of the Australian meat inspection system and observed that government officials and establishment technicians follow an established schedule to sample and examine carcasses and parts in accordance with established protocol. Such data, however, does not include findings related to carcass contamination that are routinely identified by the FSMA that conducts carcass-by-carcass verification at the end of the line.

In-plant government officials, namely OPVs and FSMAs provide inspection of production facilities, verify the performance of the AAOs who conduct post-mortem inspection, conduct carcass-by-carcass inspection, and provide certification services in accordance with a fee for service arrangement. Establishments pay for services rendered by government officials to the Office of the National Treasury of Australia, which in turn, pays the salaries of the government employees assigned to provide the aforementioned services. In the case of AAOs, they receive payment for their services directly from the establishment.

FSIS reviewed documentation that demonstrates that the CCA has promulgated regulations and manages their enforcement at slaughter/fabrication establishments certified to export raw meat products to the United States. The CCA ensures that all animals intended for slaughter receive ante-mortem and post-mortem inspection. During the onsite audit, the FSIS auditor verified that the CCA maintains regulatory presence at establishments certified to export meat products to the United States. Ante-mortem inspection is performed by the OPV or a trained FSMA. Post-mortem inspection is conducted following two approaches. A traditional approach in which FSMAs conduct all phases of post-mortem inspection and a recently introduced approach that FSIS has determined to be equivalent in which post-mortem inspection is accomplished jointly by FSMAs and AAOs. As indicated previously, AAOs are non-government officials that have been trained as food inspectors and have been authorized by the Australian government to specifically conduct post-mortem inspection duties. In both approaches, the delivery of post-mortem inspection takes place under the direct supervision of the OPVs who remains as the highest regulatory authority at certified establishments.

Records reviewed and observations made the FSIS auditor at slaughter establishments showed that government officials ensure that post-mortem inspection of slaughtered livestock is conducted in accordance with uniform instructions and performance standards developed by the CCA and consistent with the United States' requirements that call for the examination of all carcasses and parts of slaughtered livestock. OPVs and FSMAs stationed at establishments monitor the adequacy of dressing procedures, collect official verification samples of tissues to be analyzed by chemical and

microbiological laboratories, and verify that establishments collect and analyze samples of their products to verify efficacy of sanitary controls. In addition, the government inspectors report post-mortem findings and results of verification activities to the CCA by entering establishment performance information into the national databank maintained by the Australian meat inspection system.

FSIS verified that the CCA exercises ultimate control and supervision over the official inspection activities of all employees or licensees of the system by conducting regular evaluations of their performance and by promptly correcting deficiencies. The CCA ensures that OPVs and FSMA's verify that meat production activities conducted at certified establishments comply with regulatory requirements that apply to safe production of meat products for human consumption, sanitary product handling practices and controls, and construction and maintenance of facilities. Furthermore, uniform enforcement of its regulations is accomplished by disseminating regulatory issuances that provide instructions or clarification on how to enforce the regulations of the system and how to ensure compliance with export standards via automated information distribution networks.

FSIS verified that in-plant government officials receive copies of Standard Procedures (SP) and Work Instructions (WI) issued by the CCA at their stations. Furthermore, during on-site audit interviews, the CCA officials demonstrated that they were knowledgeable of the technical and administrative instructions contained in the WI. FSIS also observed that the WI issued by the CCA are based on its export standards and United States' requirements. Those WI provide methods, references, and itemized instructions to in-plant government inspectors to verify establishments' compliance with the United States' requirements. Carcass ZT Verification, WI 2.02.09, is used to verify that slaughter establishments that export meat to the United States effectively implement a HACCP plan that includes a critical control point (CCP) to prevent the presence of fecal, ingesta and milk contamination (ZT) on carcasses. However, the CCA has omitted from the instructions to in-plant inspection personnel, provisions that would instruct inspectors to document deviations from the critical control point for zero tolerance contamination (CCP-ZT) as evidence of inadequate implementation of establishments' HACCP plans, presently in-plant inspection personnel document such non-compliances, as carcass contamination incidents. FSIS reviewed records maintained by in-plant officials at several establishments and observed that entries reporting results of daily ZT-CCP verification do not relate findings of zero tolerance noncompliance to deviations from the CCP. In a similar manner, in-plant government officials do not document FSIS' reported POE-related ZT violations as events related to inadequacies in the establishments' implementation of their HACCP programs. These procedural inconsistencies in government oversight prevent establishments from accurately assessing their ability to implement their HACCP programs and could cause the CCA and establishments to inaccurately conclude that the HACCP plans are working as intended.

As it pertains to the technical competency of personnel that the CCA assigns to the certified establishments, FSIS confirmed that OPVs stationed at certified slaughter/fabrication establishments have completed academic work to earn a veterinary degree, which customarily includes courses in HACCP and Meat Science. Veterinarians also complete induction training to develop and master technical, regulatory, food safety auditing, and supervisory skills needed to perform their duties. The ultimate responsibility for delivery of inspection and verification services at the certified establishments remains with the office of the OPV. OPVs conduct ante-mortem inspection; verify adequacy of post-mortem inspection conducted by FSMA and AAOs; make post-mortem dispositions of retained

carcasses; monitor and verify compliance of establishments with their AAs; and supervise and manage inspection personnel.

Both FSMAs and AAOs assigned to conduct post-mortem inspection must earn a Meat Safety (MS) IV certificate, issued by a registered training organization and must demonstrate a satisfactory level of proficiency in the performance of meat inspection, prior to their being assigned to the full scope of post mortem inspection duties. The CCA also grants authorization to AAOs who have obtained an MS III certificate, but as a temporary 12-month appointment. This acceptance allows the candidates the opportunity to gain additional experience to obtain a MS IV certificate. The CCA provided FSIS with documentation that describes the contents of training received by both FSMAs and AAOs. A review of that information shows that both groups of the inspection force receive training that is comparable to the training received by FSIS inspectors.

The FSIS auditor observed the regulatory activities performed by FSMAs and OPVs at six slaughter establishments in which post-mortem inspection is conducted with the participation of FSMAs and AAOs. FSIS observed that there is one FSMA at the end of each slaughter line (EOL-FSMA). The EOL-FSMA verifies that each carcass is free of visual contamination and pathological lesions of food safety significance after they have passed AAOs post-mortem inspection and the CCP for ZT monitoring station. Accordingly, as per CCA instructions, when the EOL-FSMAs find ZT contamination on the carcasses, they notify the establishments, require corrective actions as per establishments' HACCP plans, and document the occurrences in the PMI record kept at their stations. The review of records conducted by FSIS showed that in-plant officials identify non-compliances, take official control actions, document all actions, and require corrective actions. However, as discussed in the HACCP component portion of this report, corrective actions do not include adequate preventive measures.

FSIS reviewed post-mortem inspection records and noted that EOL-FSMAs regularly identify ZT contamination on carcasses and document such occurrences, but CCA officials do not use that data to evaluate the adequacy of implementation of establishments HACCP plans, but rather, as an indicator of adequacy of post-mortem inspection delivery on the part of AAOs. CCA officials do not perceive repetitive CCP for ZT deviations being identified by the EOL-FSMAs as events that directly relate to inadequate implementation of the slaughter HACCP plan. Correspondingly, regulatory actions needed to correct such deficiencies are not being implemented.

Establishments that are unable to meet the standards of the export program are delisted, and their certification is suspended as part of the administrative actions instituted by the CCA. Records presented by in-plant officials demonstrate that, in response to FSIS reports of POE violations from 2011 through 2013, officials in the CCA chain of command took action to verify that establishments implemented appropriate corrective actions. When the corrective actions were deemed inadequate, the establishments were delisted by the CCA and subjected to added regulatory verification. Furthermore, the CCA has instituted a POE response policy (RP) that frames delivery of regulatory verification to be implemented to respond to POE violations. The RP provides measures to be followed when Australian meat products are involved in POE violations in a given year. Depending on whether meat products from a given establishment are found to be in violation of FSIS requirements at the United States POE once, twice or three times, the CCA will take regulatory actions that progressively go from verification activities to denial of access to U.S market when three violations take place in one year.

FSIS verified that the CCA provides oversight to its technical support by auditing the adequacy of the performance of laboratories. At the in-plant level, the FSIS auditor observed that establishments' collection, handling, and shipping of product samples for *Salmonella* and generic *E. coli* analyses to

private laboratories are overseen by in-plant government officials following procedures that FSIS previously determined to be equivalent. The laboratories of the Australian meat inspection system gain and maintain accreditation granted by the International Laboratory Accreditation Cooperation (ILAC) and the National Association of Testing Authorities (NATA). NATA is an Australian agency and a member of ILAC that provides assurances to the CCA that analytical services provided by accredited laboratories are in line with government regulations and meet market access requirements. In addition, CCA representatives and scientists conduct audits of both chemical residue and microbiological laboratories. This aspect of the system is further described in the Microbiological and Chemical Residue program components portions of this report.

The CCA is an agency of the national government of Australia that provides oversight to the meat inspection system. The CCA organizes and administers standards equivalent to those of the Federal system of meat inspection in the United States. The ongoing analysis of available data and on-site audit verification activities indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. However, as discussed above, there are two matters related to government oversight of slaughter establishments that require the attention of the CCA to ensure that establishments fully meet the regulatory HACCP requirements of the Australian meat inspection system. Specifically, the CCA instructions to in-plant inspection personnel omitted provisions that would instruct inspectors to document deviations from the critical control point for zero tolerance contamination (CCP-ZT) as evidence of inadequate implementation of establishments' HACCP plans. Additionally, inspection officials collect data that shows frequent occurrence of CCP for ZT deviations, but the CCA does not use that information as an indicator of inadequate implementation of establishments' HACCP plans.

FSIS's on-site audit, including observations, document reviews, and interviews, in combination with the agency's review of the SRT and document analysis indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level of performance for this component. However, the corrective actions implemented by the CCA must prevent recurrence of the findings reported for this component of the Australian meat inspection system.

## **V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. An equivalent inspection system operates an appropriate regulatory framework that demonstrates equivalence with FSIS requirements, including, but not limited to, HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, PMI, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to establishments eligible to export meat products to the United States.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the on-site verification phase of the audit. The FSIS auditor verified that official inspection and verification activities were in accordance with the responses provided in the SRT and supporting documentation.

FSIS' observations and reviews of government and establishment records show that the CCA of the meat inspection system of Australia has statutory authority to deliver inspection to all certified slaughter and processing establishments. Furthermore, the CCA has rules that require that official inspection

personnel, laboratories, and establishments ensure that meat products meet United States requirements. In addition, the system has regulatory requirements for continuous inspection of slaughter and processing activities at establishments that produce meat products for the United States market, control of inedible and condemned materials, and periodic supervisory reviews of certified establishments.

FSIS verified that all animals presented for slaughter undergo ante-mortem inspection, which is conducted by the OPV at small establishments and with the assistance of an FSMA, at large establishments. CCA officials verify that livestock arrive to slaughter establishments accompanied by required documentation that allows the system to trace products back to primary centers of production. During ante-mortem inspection, officials detect abnormalities in livestock presented for slaughter and input inspection results into a data bank managed by the CCA. In-plant government inspectors also evaluate the adequacy of ante-mortem facilities and assess compliance of establishments with humane handling requirements imposed by the CCA and required by importing countries.

In March 2011, FSIS announced in Federal Register/Vol. 76, No 42, Docket No. FSIS-2009-0020 that the alternative system of post-mortem inspection that Australia proposed to use in establishments included in its Australian Export Meat Inspection System (AEMIS) was equivalent to the method used by FSIS. In that alternative, post-mortem inspection (PMI) is conducted with the participation of FSMAs and AAOs at specific livestock slaughter establishments. Following that equivalence determination, Australia gradually proceeded to implement that equivalent PMI alternative at establishments certified to export meat products to the United States that were grouped under AEMIS. During this on-site audit, the CCA informed FSIS that the acronym "AEMIS" no longer strictly identified those establishments that operate using the PMI alternative system described above, but rather identified the system of meat inspection that Australia employed at all establishments exporting meat products. As indicated by the CCA, within the AEMIS there are now slaughter/fabrication establishments certified to export to the United States that operate using two PMI systems. One group of establishments uses the traditional PMI system, where only FSMAs, who are employees of the Australian government, conduct inspection of heads, viscera, and carcasses. And the other group, which uses the PMI alternative system, where AAOs, who are establishment employees working under a NIC agreement, conduct post-mortem inspection of heads, viscera and carcasses on the line and one FSMA, who is a government inspector stationed at the end-of-line (EOL-FSMA), performs carcass-by-carcass inspection.

Furthermore, the alternative PMI can be delivered following two configurations of inspection stations. In one configuration, the EOL-FSMA performs carcass-by-carcass inspection at a station located on the line, after the AAO's head, viscera, and carcass inspection stations. In the other configuration, the AAO head and viscera inspection stations remain on the line and the AAO carcass inspection station is eliminated. In that arrangement, the EOL-FSMA alone performs carcass-by-carcass inspection on each slaughter line.

During this onsite audit, FSIS observed that the alternative PMI, where the EOL-FSMA is stationed at the end of the line after the AAO carcass inspection station, was being used at all six certified establishments audited. The FSIS auditor verified that AAOs are permitted to conduct PMI only after the CCA headquarters office issues to the OPV documents that show that AAOs have received authorization to perform PMI and upon successful evaluation of their competence on the line, as assessed by the OPVs. In addition, the establishments present heads, viscera, and carcasses properly

identified for inspection. The design of the inspection stations meets equivalent requirements, and the EOL-FSMAs demonstrated an acceptable level of proficiency to perform their inspection duties. FSIS also verified the functions of the OPVs as they verified the adequacy of PMI conducted by AAOs and the performance of FSMAs. FSIS was not able to assess the second configuration of the alternative PMI, since all audited establishments operated with the EOL-FSMA situated on the line after the AAO carcass inspection station.

FSIS observed that OPVs exert their legal authority to adjust production rates to ensure adequate PMI and maintenance of sanitary dressing activities. Furthermore, OPVs report to plant management the results of daily verification of PMI and ensure that deficiencies in the performance of AAOs are promptly addressed by the establishments. Records reviewed by FSIS showed that OPVs or their designees assess daily the technical competency of the AAOs by monitoring the accuracy and consistency of their PMI decisions. For that purpose, DAFF officials follow instructions provided by the CCA in WI 3.03.01, which describes the verification procedure, responsibilities, and actions to be taken when non-conformances are identified.

The FSIS auditor verified that the CCA requires establishment operators to adhere to their AAs and ensure that their premises are properly built and maintained in good repair to prevent the creation of insanitary conditions. The auditor confirmed that in-plant officials verify that operators of certified establishments meet the regulatory requirements of the Australian meat inspection system. Government officials regularly evaluate the conditions in the different areas of the establishments, document their findings, and require that operators implement adequate corrective actions. Documents reviewed by FSIS during the audit indicate that operators of the establishments and government officials interact to ensure that non-compliances related to maintenance of the facilities are identified and addressed to comply with the regulations of the program. However as further described in the Sanitation component of this report, in-plant officials need to assess in a more critical manner the implementation of sanitation programs to identify and require abatement of potential sources of product contamination.

FSIS determined that, in accordance with the rules of the Australian meat inspection system, OPVs conduct regular on-site reviews of the performance of the food safety systems of the establishments utilizing the AAs of the establishments as standards. ATMs also conduct periodic evaluations of the performance of in-plant officials and verify the level of regulatory compliance maintained by certified establishments. Periodic evaluations are also conducted by FOMs who assess establishments' performance. They verify corrective actions to deficiencies identified by foreign auditors, and to FSIS's reports of POE violations. FSIS reviewed records and reports generated by the OPVs to document assessments of the establishments AAs and verified that deficiencies are identified, documented, and corrected by the establishments. Reports of ATMs' reviews were also evaluated and seen to adequately document results of reviews and follow-up activities needed to correct deficiencies. However, the reports of the reviews do not indicate whether the results of carcass examination conducted by the FSMA at the end of the slaughter line were included in the assessment of adequacy of corrective actions.

FSIS observed ATMs as they assessed the food safety systems of certified establishments by conducting evaluations of production areas and reviewing documentation generated and maintained by the operators of the establishments and in-plant inspection personnel. The manner in which the ATMs conducted the establishment reviews demonstrated to FSIS that the CCA maintained adequate regulatory oversight over the production functions of the establishments in accordance with Australian regulations.

Furthermore, forms, records, and reports presented to FSIS for review indicated that, to ensure standardized audit approaches, capture data, and review reports, the CCA uses an automated data management system known as the National Establishment Verification System (NEVS). The NEVS ensures that results of verification activities are reported following a uniform protocol in accordance with CCA instructions, parameters, and established policies.

The FSIS auditor verified that OPVs and ATMs input data into the system as they complete reports of audit outcomes. OPV also compiles results of daily verification activities conducted by the establishment, and inspection personnel at the end of each month and sends it to CCA headquarters. The system then processes the data and generates output that reaches the OPVs and establishments approximately one month after submission. Government officials at several levels can access and analyze the data to determine compliance levels maintained by establishments and performance trends developing at local and national levels. Furthermore, the collected data allow the CCA to identify establishments that require greater official oversight. FSIS observed that the resident veterinarians and ATMs could access the databank from the establishments' offices and were proficient at gathering and filtering data to generate examples of work instructions, PMI summaries, and daily inspection reports.

The MISA has legal authority and a well-documented regulatory framework to implement requirements equivalent to those governing the United States' system of meat inspection. The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level of performance for this component.

## **VI. COMPONENT THREE: SANITATION**

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. An equivalent inspection system provides requirements for sanitation, sanitary handling of products, and development and implementation of sanitation standard operating procedures that demonstrate equivalence with FSIS requirements.

The evaluation of this component included a review and analysis of the information provided by the CCA in the sanitation component portions of the SRT, observations gathered during the on-site verification audit of six slaughter establishments and their corresponding DAFF local offices. FSIS reviewed legislation, regulations, and official instructions to verify that the CCA has and exercises legal authority to require establishments to develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions.

FSIS determined that the CCA requires that establishments operate in a manner that prevents the creation of insanitary conditions, and that establishments develop written programs that they are to follow to prevent direct product contamination. Official verification of compliance with that requirement is performed by government inspectors who regularly assess the conditions and maintenance of the facilities at all certified establishments, review of their written sanitation procedures, and evaluate their implementation. Establishments are also required to monitor adequacy of their facilities, conduct analysis of product and personnel flow, develop maintenance programs for equipment and structures, and develop methodology to classify the severity of the deficiencies. CCA officials verify that the written sanitation programs prepared by the establishments describe the procedures they will follow to ensure that all product contact surfaces will be cleaned and sanitized prior to the

beginning of production, along with what measures that they will implement to prevent direct product contamination throughout the production day.

FSIS verified onsite the functions of the ATMs and OPVs as they evaluated the sanitary conditions of the plants and reviewed electronic and hard copy documents, as well as monitoring and verification records. The FSIS verification activities also included an assessment of the modified sanitary dressing procedures that the CCA reported to FSIS as part of the corrective actions implemented by the establishments to address POE violations involving the presence of *E. coli* O157:H7 and ZT contamination on raw beef products reported by FSIS in fiscal year 2011 and 2013. The FSIS auditor observed that, as proffered in the corrective actions presented by the CCA, establishments have modified their kill floors to better prevent gastric contents spillage and cross-contamination of carcasses. Flow of carcasses has been modified and pieces of equipment repositioned to improve sanitary handling of slaughtered livestock. Furthermore, in-plant officials assess the level of cleanliness of arriving livestock and require that the establishments adjust slaughter line speeds accordingly. Inspection records also demonstrated that in-plant government officials regularly inspect the facilities and document deficiencies that are corrected and verified as part of the procedure prescribed by the CCA.

FSIS observed government officials as they assessed the adequacy of pre-operational and operational sanitation monitoring and verified that officials evaluated the sanitation program of the establishments. However, at three of the six audited establishments, there were sanitary concerns that had not been identified by the OPV.

- At one of the establishments, numerous conveyor belts had become frayed. Standing surfaces had deteriorated, which created surfaces difficult to clean and sanitize.
- At another establishment, there was clutter in the packaging supplies storage room, and trash had accumulated in several areas, in close proximity to direct product contact surfaces.
- At a third establishment, while observing dressing of sheep, an automatic hide puller was seen causing contaminated hides to come in contact with skinned surfaces of other un-eviscerated carcasses.

These findings, although addressed by prompt corrective measures by the establishments, indicate that establishments need to monitor better the sanitary conditions of their equipment and facilities. In addition, in-plant officials need to assess in a more critical manner the implementation of sanitation programs to identify and require abatement of potential sources of product contamination.

Australia's meat inspection system has legal authority and a well-documented regulatory framework to implement requirements equivalent to those governing the United States' system of meat inspection. The sanitation concerns identified by FSIS were promptly addressed with short-term corrective actions, and CCA officials will ensure that proper implementation of long-term corrective actions takes place where necessary. The audit observations support that the CCA continues to maintain equivalence and is operating at an "adequate" level of performance for this component. However, implementation of adequate corrective actions to address the above reported findings will improve the performance of this component of the Australian meat inspection system.

## **VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The component pertains to the requirement that an inspection system must have regulatory requirements for certified establishments to develop, implement, and maintain HACCP programs as set forth in the regulations of FSIS.

The auditor evaluated this component by reviewing and analyzing information provided by the CCA in its SRT and by auditing on-site the performance of establishments, laboratories, and government sectors of the system.

Documents reviewed by the FSIS auditor included regulatory standards, training materials, and regulatory guidelines issued by the CCA. FSIS also assessed the adequacy of HACCP program verification activities conducted by government officials and establishment operators at the establishment level by observing on-site verification activities and by reviewing electronic and hard copy versions of monitoring and verification records generated by operators and in-plant government officials. Documents reviewed also included reports presented by the CCA in response to multiple POE violations related to the United States' requirement for ZT for fecal, ingesta and milk contamination on meat products reported by FSIS from April 2011 through June 2013. The observations, review of documents, and analysis of information conducted by FSIS revealed that the Australian meat inspection system imposes regulatory requirements for the development, implementation, and maintenance of HACCP programs in certified establishments that include the slaughter HACCP plan and a CCP to control ZT. Furthermore, FSIS verified that in-plant officials and ATMs periodically assess the adequacy of establishments' HACCP programs. Records and documents reviewed and on-site observations indicate that CCA officials assess the design and execution of the HACCP programs, including the adequacy of the hazard analysis, monitoring of CCPs, corrective actions, record keeping, and verification activities. CCA officials also conducted HACCP program reviews in response to POE violations and concluded that the programs were reportedly working as intended. However, the evaluation of the HACCP systems' implementation that the FSIS auditor conducted at the six audited establishments identified the following concerns:

- The six establishments conduct carcass examination at the CCP for ZT based on monitoring frequencies provided in government guidelines. With this approach, establishments are allowed to use a reduced monitoring frequency recommended for establishments in good status, i.e., examining 32 to 45 half carcasses per shift. However, that monitoring frequency does not adequately detect deviations from the critical limit. This practice results in numerous deviations from the ZT critical limit that are detected by the FSMAs stationed at the end of the slaughter line, rather than being detected at the CCP monitoring station, as the establishments' HACCP plans require.
- Establishments respond to the numerous CCP-ZT deviations reported by the FSMAs stationed at the end of the slaughter line by implementing pertinent corrective actions in accordance with their HACCP plan to ensure the CCP will be under control after the corrective action is taken. However, measures to prevent recurrence of deviations are either not instituted or inadequately implemented by the establishments.

- Establishments' records show as the root cause of ZT-CCP deviations, inadequate performance of AAOs' PMI duties, rather than the shortcomings in the dressing process that cause the contamination events. This inadequate assessment of the actual cause of the reported CCP-ZT deviations prevents the establishments from instituting adequate corrective actions.
- The six audited establishments operate under a newly introduced system of post-mortem inspection that affects the slaughter process. Following introduction of such changes, the establishments did not reassess their HACCP plans, even when FSMAs repetitive CCP- ZT deviations bring into question the adequacy of implementation of their slaughter HACCP plans.

The FSIS auditor verified that establishments and government offices have responded to fourteen POE violations reported by FSIS from October 2011 through September 2013 that included ten instances of ZT deviations related to fecal matter and ingesta on meat products. The CCA and the establishments involved have responded to FSIS reports by conducting investigations, redesigning their kill floors to prevent carcass contamination, and assessing the adequacy of the establishments' HACCP plans. However, the CCA verification activities were incomplete, as made evident by the findings described above.

The CCA indicated during the exit conference that it would address the above-discussed concerns related to the HACCP component of the system by requiring that establishments monitor the CCPs in their HACCP plans at an appropriate frequency and ensure that the establishments adequately identify the root causes of CCP deviations to initiate corrective actions to effectively prevent recurrence. Furthermore, all establishments that have adopted the alternate post-mortem inspection system will reassess their HACCP plan to verify that the changes introduced do not have an impact on the implementation of their food safety controls.

The document analyses and on-site audit verification of the meat inspection system of Australia indicate that at the time of the onsite audit, the CCA was nominally able to demonstrate that the HACCP component of its system continues to meet core equivalence requirements. The reported findings for this component make evident verification and reassessment inadequacies in the implementation of HACCP systems. Specifically, the CCP for ZT included in the HACCP plans of slaughter establishments does not work as designed to control ZT contamination. Furthermore, the CCA verification efforts are inadequate to effectively ensure that slaughter establishments control ZT contamination. It is therefore of important that the CCA implement prompt corrective actions to address the above reported findings and provide to FSIS a report on the adequacy of their implementation within the next sixty days.

## **VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAM**

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residues Control Programs. This component pertains to regulatory requirement that the inspection system have a chemical residue control program that is organized and administered by the national government. The program must include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

An assessment of the CCA's residue control program was conducted by reviewing the information provided through SRT, as well as the 2011-2012 National Residue Survey (NRS) results report submitted by Australia and visits to government offices and slaughter establishments. The FSIS auditor verified that the CCA has delegated the responsibility to maintain monitoring and surveillance of animals and animal products to detect evidence of chemical residues in edible tissues to the NRS. The auditor also established that the NRS is an operational unit of the FD that manages food safety and residue controls. In accordance with the statute that governs food safety in Australia, the NRS identifies potential problems and provides guidance to other organizations where there is a need for control or follow up to address violations or emerging issues related to the presence of chemical residues and contaminants in food.

Official documents reviewed by FSIS indicate that the NRS operates within a statutory framework that permits it to finance its functions on a full-cost recovery basis. Industries pay for the analytical services provided to the NRS which, in turn, pays the laboratories when they receive an invoice, and when the analysis of the results is conducted. Results of the analyses provide the CCA with indicators of the adequacy of chemical residue controls at primary centers of production. The database that laboratory analyses generate is managed and packaged by the NRS, which distributes quarterly and annually reports of analytical results to stakeholders and trading partners.

Additional information provided by the CCA to FSIS indicates that factors considered when determining the annual monitoring residue program include: registered use of a particular chemical, likely occurrence of residues, extent and pattern of use, incentives for misuse, persistence of the compound in the environment, past monitoring results, availability of suitable analytical methods, testing capacity and laboratory proficiency, testing arrangements, specific overseas requirements, and perceptions of the residue as a possible public health hazard.

FSIS verified that NRS manages national random and targeted testing programs for chemical residues in agricultural commodities in consultation with industry and the sectors of the CCA that participate in the testing of food products. The design of the testing programs and operational processes that include sample collection, shipping to laboratories, management, and analysis of data and initiation of trace-back activities are also managed by NRS. However, analysis of samples is delegated to laboratories that NRS contracts through a competitive tender process.

The type of oversight the CCA provides to the functions of chemical laboratories was also assessed by FSIS. All laboratories are accredited by NATA and evaluated by NRS prior to being awarded three year contracts to analyze samples. Once integrated into the program, the contracted laboratories continue using the methods of analysis evaluated at the time of their assessment, and participate in proficiency testing via inter-laboratory and intra-laboratory check sample programs. The NRS audits the laboratories periodically to evaluate their performance, assessing their technical and managerial competence in accordance with ISO 17025 standards, NATA standards, CCA and United States' requirements.

FSIS ongoing equivalence audit included review of documents provided by the CCA and records of NRS past evaluations that document that the laboratories are being adequately overseen by the Australian government. Furthermore, FSIS verified that government inspectors collect samples in accordance with standard operating procedures, as instructed by NRS and -- when in the professional

judgment of the OPV --, sampling of animal tissues is deemed necessary to establish their acceptability as a source of human food. Collected samples are sent to the laboratories for analyses via a Central Receiving and Dispatch site in Canberra. FSIS also verified that provisions of the regulatory controls managed by the CCA confer legal authority upon in-plant officials to condemn food products when laboratory analysis indicates the presence of chemical residues at a level that exceeds Australian standards.

The NRS report for the period of July 2011-June 2012 shows three instances in which meat products eligible for export to the United States were found to be unacceptable. One out of 330 fat samples tested from cattle exceeded Australian standards for macro cyclic lactones, and two out of 970 samples of bovine liver exceeded Australian standards for sulfonamides during this time period. In each instance, the Australian authorities conducted a trace-back investigation to determine the likely cause of the events, issued warning letters to the producers, and provided advice on adequate recordkeeping to livestock owners. The CCA has a chemical residue control program that is organized and administered by the national government in accordance with United States' requirements.

The document analyses and on-site audit verification of the Chemical Residues Control Program component criteria indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. The CCA meets this component at an "average" level of performance.

## **IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS**

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological analysis programs that the CCA of the MISA organizes and administers to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome.

To determine ongoing equivalence of this component, FSIS reviewed the responses provided by the CCA in the Pathogen Reduction Standards section of its SRT that describe Generic *E. coli* and *Salmonella* sampling, as well as Australia's *E. coli* O157:H7 and non-O157 Shiga toxin producing *Escherichia coli* (STEC) control program. In addition, FSIS assessed on-site the daily implementation of the microbiological sampling and testing of raw meat product activities conducted by establishments and laboratories. FSIS also verified the adequacy of the corrective actions implemented by the sectors of the MISA to address POE violations reported by FSIS from May 2011 through March 2013, which related to the presence of *E. coli* O157:H7 in raw beef products.

The documents reviewed during this ongoing equivalence audit demonstrate that the CCA administers a national regulatory microbiological monitoring program for establishments producing meat products for export to the United States. The program provides indicators of the adequacy of sanitary dressing procedures and production practices and verification of effectiveness of establishments' food safety controls designed to control microbiological pathogens.

FSIS confirmed that laboratories conducting microbiological analysis of meat samples are participants of the Approved Laboratory Program (ALP) of DAFF. Laboratories participating in the ALP conduct microbiological analyses of edible meat products from certified establishments. Prior to testing the

products, the laboratories successfully complete an evaluation of their performance conducted by NATA. Laboratories also submit their scope of accreditation, an agreement to participate in proficiency testing programs, and the details of the approved laboratory methods they intend to use to analyze products. ALP laboratories are audited annually by NATA or DAFF, in accordance with the requirements specified in ISO/IEC 17025 and participate in proficiency testing every 6 months to maintain accreditation for the analytical methods in their scope.

FSIS audited two microbiological laboratories during the on-site verification portion of this audit and reviewed official documents including reports and records generated by DAFF and NATA experts that contained results of evaluations, proficiency tests, and verification of corrective actions. The FSIS auditor verified that NATA and DAFF audits of the two laboratories visited had assessed acceptability of laboratory conditions, scope of accreditation, adequacy of records generated, and corrective actions taken to address results of past audits in accordance with the guidance provided by ISO 17025. FSIS established that the CCA maintains oversight of these two laboratories to ensure that they follow official protocols and perform their functions adequately.

Documents reviewed by FSIS and observations made at certified slaughter establishments demonstrate that testing of raw products for Generic *E. coli* and *Salmonella* is conducted at slaughter facilities. Collection of random samples along with their shipping and handling is done by the establishments under the supervision of in-plant government inspection officials and in accordance with instructions issued by the CCA in the *E. coli* and *Salmonella* monitoring program for export-slaughter establishments. The samples are analyzed at CCA-approved, NATA-accredited laboratories that report results of the analyses to CCA officials and establishments at the same time. Generic *E. coli* results are quantified and reported in colony forming units per square centimeter (cfu/cm<sup>2</sup>). *Salmonella* results are qualitatively assessed, i.e. detected or not detected.

The FSIS auditor assessed the implementation of the microbiological verification activities overseen by the CCA in-plant and verified that certified slaughter establishments conduct microbiological sampling of carcasses and parts in accordance with official protocols. In addition, in-plant officials verify the adequacy of implementation of sampling and analysis protocols, and track and evaluate sampling results. Furthermore, government officials enter reported results into the national *E. coli* and *Salmonella* Monitoring Program (ESAM) MeatTech Database, which is managed by the CCA to track establishments' performance and to analyze the national status of microbial control strategies.

The regulations imposed by the CCA upon producers to control *Salmonella* in raw meat products require that three consecutive failures to meet the salmonella control standards is deemed by the Australian authorities as a failure to maintain the minimum standard for slaughter hygiene and sanitation. This brings into question the adequacy of the HACCP plan of the establishment. Accordingly, the CCA would impose regulatory sanctions consistent with the statutory frameworks of the Australian meat inspection system and exclude such operator from the exports program.

FSIS also assessed the *E. coli* O157:H7 control program managed by the CCA. Documents reviewed included the results of testing of raw ground beef components for the *E. coli* O157:H7 program provided by the CCA and records maintained by the establishments. The CCA requires test and hold for all lots of raw ground beef components destined for the United States and verification of the testing programs used by the establishments to determine that they meet the requirements of the MISA. In addition, the CCA

tests raw ground beef components destined for the United States at least monthly. The CCA revised this protocol to include the additional STECs of concern and presented it to FSIS in July 2013, in the self-reporting tool, for determination of continued equivalence. Samples collected by the establishment and government officials are analyzed in CCA-approved laboratories.

FSIS evaluated the ability of government officials to provide oversight over the collection and handling of samples for *E. coli* O157:H7 analysis and verified that plant employees adhere to proper aseptic protocols. They also confirmed that the officials conducted identification and handling of samples in an adequate manner. Government officials adequately verified that identification of collected samples was consistent with CCA requirements.

FSIS verified the corrective actions implemented by the CCA to address the finding reported during the 2011 audit that related to an apparent discrepancy between the confirmation rates reported by Australian laboratories and FSIS' laboratories for the detection of *E. coli* O157:H7 in raw beef products. Document reviews and interviews conducted at the laboratories and government offices demonstrated that the CCA had aligned terminology used to report laboratory results with the nomenclature currently in use in the United States. In addition, the CCA introduced improvements to analytical methodology to improve screening of samples by requiring the use of additional enrichment steps, eliminating the use of lateral flow devices and introducing polymerase chain reaction based screening technologies. Confirmation protocols were also revised to require that Cefixime-Tellurite Supplemented Sorbitol MacConkey Agar with Rainbow Sugar be used in the confirmation procedures.

An additional aspect of this component that FSIS verified during this audit was the adequacy of implementation of corrective actions that the CCA proffered to address POE violations related to detection of *E. coli* O157:H7 in Australian raw beef products that were reported in fiscal years 2012 and 2013. The verification was conducted by assessing the measures implemented by the CCA and establishments. Inspection records show that in four instances in which this type of POE violation was reported by FSIS, CCA officials conducted investigations that included assessments of the establishments' microbiological testing programs, sanitation programs, and implementation of HACCP plans. The on-site observations and record reviews conducted by FSIS showed that the establishments modified the design of their slaughter rooms to improve cattle dressing activities and better control contamination. Furthermore, sample collection procedures were modified to include all products from a production day shift, and analytical procedures were modified to respond to the mandated changes introduced by the CCA to improve detection of *E. coli* O157:H7.

The microbiological testing programs component of the MISA is organized and administered by the national government to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with the United States requirements. The document analyses and on-site audit verification of the Microbiological Testing Programs component indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. At this time, the CCA's microbiology testing program operates at an "average" level of performance.

## **X. CONCLUSIONS AND NEXT STEPS**

Throughout the equivalence verification audit, the FSIS auditor assessed Australia's performance with regard to each of the components of the Australian meat inspection system, while evaluating the adequacy of the corrective actions that the system implemented to address the audit finding reported during the FSIS 2011 audit and repeat POE violations. The audit activities also included verification of the alternative PMI system previously identified as AEMIS to determine whether its implementation is consistent with the design presented by the CCA to FSIS for equivalence determination.

The CCA has continued to implement the alternative PMI at certified establishments in a manner that is consistent with the design that FSIS determined to be equivalent in March 2011. The corrective actions proffered to address past audit findings have been adequately implemented. The CCA has developed a policy to control establishments involved in repeated POE violations, and establishments have introduced measures within their processes that are expected to prevent recurrence of POE violations. However, FSIS POE records show that in the latter portion of calendar year 2013, beef products shipped to the United States from Australian meat establishments continue to be involved in violations of United States food safety standards. In addition, as reported in the corresponding sections of this report, the issues summarized below, related to the Government Oversight, Sanitation, and HACCP components of the system require the attention of the CCA:

- CCA Work Instructions to verify adequacy of implementation of HACCP plans omitted provisions that would instruct inspectors to document deviations from the critical control point for zero tolerance contamination (CCP-ZT) as evidence of inadequate implementation of establishments' HACCP plans. Instead, inspectors are instructed to document such non-compliance as carcass contamination incidents. Additionally, inspection officials collect data that show frequent occurrence of CCP-ZT deviations, but the CCA does not use that information as an indicator of inadequate implementation of establishments' HACCP plans.
- In-plant officials have not critically assessed sanitation programs, their implementation, and their ability to identify and require abatement of potential sources of product contamination. Monitoring of sanitary conditions of equipment within establishments is also inadequate.
- The CCA has not ensured that establishments adequately implement their HACCP plans including monitoring the CCPs at an appropriate frequency, adequately identify the root causes of CCP deviations, and adequately institute corrective actions to prevent their recurrence. The CCA has not ensured that all establishments that have adopted the alternative post-mortem inspection system have reassessed their HACCP plans.

The audit results indicate that Australia's food safety inspection system continues to maintain equivalence with the United States system and is operating at an "adequate" level of performance. The CCA meets the core criteria for all six equivalence components. However, the reported findings for the HACCP component make evident inadequacies in the implementation of HACCP systems. Specifically, the CCP for ZT included in the HACCP plans of slaughter establishments does not work as designed to control ZT contamination. Furthermore, the CCA verification efforts are inadequate to effectively ensure that slaughter establishments control ZT contamination. In addition, FSIS POE records show that in the latter portion of calendar year 2013 and the first part of 2014, beef products shipped to the United States from Australian meat establishments continue to be involved in violations of United States food safety standards related to ZT violations. During the exit meeting, the CCA noted that it had initiated immediate and long-term actions to address the above audit observations. FSIS expects that the CCA will implement prompt corrective actions to address the above reported findings and provide to FSIS a report on the adequacy of their implementation within the next sixty days.

Upon receipt of the draft final audit report, the CCA provided comments addressing the findings contained in the report. That information is included in Appendix B of this final report.

## APPENDICES

**APPENDIX A: Australia's Establishment Audit Checklists**

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Fletcher International Exports Pty., Ltd. Lot 11, Yarrandale Road Dubbo, New South Wales, 2830 Australia	2. AUDIT DATE August 7, 2013	3. ESTABLISHMENT NO. Australia 2309	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Slaughter Establishment No. 2309, Fletcher International Exports Pty., Ltd.

Products from this establishment were involved in multiple port of entry (POE) violations related to zero tolerance contamination (ZTC). The CCA has suspended eligibility of this establishment for export to the U.S. and continues to assess its performance on a monthly basis to determine if it should be relisted.

22. Each POE instance triggered a corrective action request (CAR) issued to the establishment. However, the CARs do not describe the POE violations as HACCP regulatory non-compliance but as production of unwholesome product detected at U.S. POE, thus failing to recognize that there are deficiencies in the implementation of the establishment's HACCP plan.

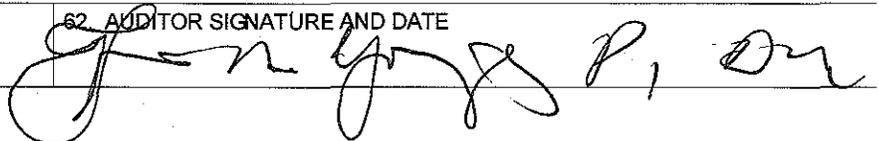
A review of records showed that past DAFF reviews brought to the attention of the establishment the inadequacy of recorded preventive measures. However, the FSIS auditor observed that the preventive measures being recorded continued to be ineffective or not adequately implemented. DAFF officials will reemphasize this concern again before the establishment managers as part of the issues pending resolution.

18. At this establishment, there are also three approaches in place used by plant management and government officials to assess carcasses to ensure that they comply with regulatory requirement for ZT controls. The establishment has a critical control point (CCP) in its HACCP plan that is designed to ensure that only carcasses that are free of ZTC leave the slaughter room. The establishment also conducts meat hygiene assessment (MHA) of the carcasses held in the holding coolers. In these two approaches the establishment documents the results of the assessments and institutes corrective actions when carcasses with ZTC are identified. Additionally, Department of Agriculture, Fisheries and Forestry in-plant officials (DAFF) verify the monitoring of the CCP by sampling carcasses in the slaughter floor and conduct MHA in the holding chillers. In those two approaches, DAFF verify the adequacy of corrective actions implemented by the establishment when carcasses with ZTC are identified by either the establishment or government verifiers.

The third approach involves the DAFF-food safety meat assessor (FSMA) stationed at the end of the evisceration line, past the company carcass inspectors, trimmers and the CCP monitoring station in the slaughter room. This government official is responsible for identifying pathological lesions and ZTC that the establishment failed to address. When the FSMA identifies ZTC, follows official work instructions and requests immediate corrective action. However, his finding is not considered by DAFF as a deviation from the CCP for ZTC. As such, the only record made of the occurrence is a brief notation made by the FSMA's on the official inspection record without indicating that the occurrence was a HACCP regulatory non-compliance. In conclusion, the current regulatory approach being implemented by DAFF does not ensure adequately that this establishment meets U.S. requirements related to HACCP.

61. NAME OF AUDITOR  
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION JBS Australia Pty., Ltd. 2 Lock Way Riverview Queensland 4303 Australia	2. AUDIT DATE August 9, 2013	3. ESTABLISHMENT NO. Australia 235	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Slaughter Establishment No. 235, JBS Australia Pty., Ltd.

Products from this establishment were involved in a port of entry (POE) violation related to *E. coli* O157:H7.

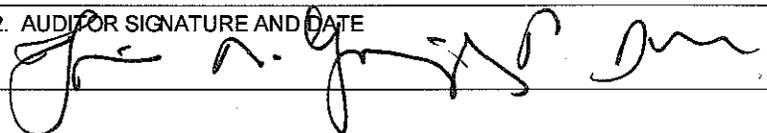
39. FSIS auditor observed that during verification of pre-operational sanitation, Australian officials omitted to assess and report that floor surfaces in the deboning room had become deteriorated and created many areas that were difficult to clean. In addition, the FSIS auditor identified fragments of meat and fat that were trapped under the edges of floor panels at junction points. Several overhead structures had peeling paint and some had accumulated corrosion on their surfaces. Conveyor belts in the cutting and fabrication room, which run in close proximity to unpackaged product were frayed at the edges and had become difficult to clean.

18. At this establishment, there are also three approaches in place used by plant management and government officials to assess carcasses to ensure that they comply with regulatory requirement for ZT controls. The establishment has a critical control point (CCP) in its HACCP plan that is designed to ensure that only carcasses that are free of ZTC leave the slaughter room. The establishment also conducts meat hygiene assessment (MHA) of the carcasses held in the holding coolers. In these two approaches, the establishment documents the results of the assessments and institutes corrective actions when carcasses with ZTC are identified. Additionally, Department of Agriculture, Fisheries and Forestry in-plant officials (DAFF) verify the monitoring of the CCP for ZTC by sampling carcasses in the slaughter floor and conduct MHA in the holding chillers. In those two approaches, DAFF verify the adequacy of corrective actions implemented by the establishment when carcasses with ZTC are identified by either the establishment or government verifiers.

The third approach involves the DAFF-food safety meat assessor (FSMA) stationed at the end of the evisceration line, past the company carcass inspectors, trimmers and the CCP monitoring station in the slaughter room. This government official is responsible for conducting final post mortem inspection of carcasses by identifying pathological lesions and ZTC that the establishment failed to address. When the FSMA identifies ZTC, follows official work instructions and requests immediate corrective action. However, his findings are not considered by DAFF as a deviation from the CCP for ZTC. As such, the only record made of the occurrence is a brief notation made by the FSMA's on the official inspection record without indicating that the occurrence was a HACCP regulatory non-compliance. In conclusion, the current regulatory approach being implemented by DAFF does not ensure adequately that this establishment meets U.S. requirements related to HACCP.

61. NAME OF AUDITOR  
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Northern Cooperative Meat Co.Pty., Ltd. 10615 Summerland Way Casino, New South Wales, 2470 Australia	2. AUDIT DATE Aug. 12, 2013	3. ESTABLISHMENT NO. Australia 239	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Slaughter Establishment No. 239, Northern Cooperative Meat Co. Pty., Ltd.

Products from this establishment were involved in port of entry (POE) violations related to *E. coli* O157:H7.

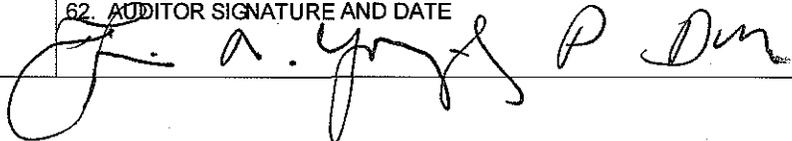
38/46. During the tour of the facilities during operations the FSIS auditor and Department of Agriculture, Fisheries and Forestry in-plant officials (DAFF) observed one mouse on the exterior areas, in the vicinity of the path that leads from the inspection office to the production areas. As a follow up to the sighting, the FSIS auditor proceeded to verify the sanitary conditions in the dry storage area and found that several pallets of packaging supplies had been damaged and remained in storage cluttering several areas in the room. The placing of the pallets prevented adequate inspection of the storage room. Trash had accumulated in corners and many areas showed that housekeeping was not being adequately implemented. DAFF officials made a record of these findings and proceeded to request corrective action for both inadequate housekeeping and inadequate pest control.

18. At this establishment, there are also three approaches in place used by plant management and government officials to assess carcasses to ensure that they comply with regulatory requirement for ZT controls. The establishment has a critical control point (CCP) in its HACCP plan that is designed to ensure that only carcasses that are free of ZTC leave the slaughter room. The establishment also conducts meat hygiene assessment (MHA) of the carcasses held in the holding coolers. In these two approaches, the establishment documents the results of the assessments and institutes corrective actions when carcasses with ZTC are identified. Additionally, DAFF verify the monitoring of the CCP for ZTC by sampling carcasses in the slaughter floor and conduct MHA in the holding chillers. In those two approaches, DAFF verify the adequacy of corrective actions implemented by the establishment when carcasses with ZTC are identified by either the establishment or government verifiers.

The third approach involves the DAFF-food safety meat assessor (FSMA) stationed at the end of the evisceration line, past the company carcass inspectors, trimmers and the CCP monitoring station in the slaughter room. This government official is responsible for conducting final post mortem inspection of carcasses by identifying pathological lesions and ZTC that the establishment failed to address. When the FSMA identifies ZTC, follows official work instructions and requests immediate corrective action. However, his finding is not considered by DAFF as a deviation from the CCP for ZTC. As such, the only record made of the occurrence is a brief notation made by the FSMA's on the official inspection record without indicating that the occurrence was a HACCP regulatory non-compliance. In conclusion, the current regulatory approach being implemented by DAFF does not ensure adequately that this establishment meets U.S. requirements related to HACCP.

61. NAME OF AUDITOR  
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE

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United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Southern Queensland Exporters Pty., Ltd. Longs Lane Wallangara, Queensland, 4383 Australia	2. AUDIT DATE Aug. 13, 2013	3. ESTABLISHMENT NO. Australia 344	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Slaughter Establishment No. 344, Southern Queensland Exporters Pty., Ltd.

Products from this establishment were involved in port of entry (POE) violations related to zero tolerance contamination (ZTC).

46. During the tour of the facilities during operations, the FSIS auditor observed that hides did not slide freely from the clamp of the automatic hide puller, but remained stuck to the clamp. As the clamp of the hide puller continued its motion, it clamped the next hide, causing the unreleased hides to come in contact with the skinned surfaces of the carcasses. Department of Agriculture, Fisheries and Forestry in-plant officials (DAFF) notified the establishment and immediate corrective action was implemented.

18. At this establishment, there are also three approaches in place used by plant management and government officials to assess carcasses to ensure that they comply with regulatory requirement for ZT controls. The establishment has a critical control point (CCP) in its HACCP plan that is designed to ensure that only carcasses that are free of ZTC leave the slaughter room. The establishment also conducts meat hygiene assessment (MHA) of the carcasses held in the holding coolers. In these two approaches the establishment documents the results of the assessments and institutes corrective actions when carcasses with ZTC are identified. Additionally, DAFF verify the monitoring of the CCP by sampling carcasses in the slaughter floor and conduct MHA in the holding chillers. In those two approaches, DAFF verify the adequacy of corrective actions implemented by the establishment when carcasses with ZTC are identified by either the establishment or government verifiers.

The third approach involves the DAFF-food safety meat assessor (FSMA) stationed at the end of the evisceration line, past the company carcass inspectors, trimmers and the CCP monitoring station in the slaughter room. This government official is responsible for conducting final post mortem inspection of carcasses by identifying pathological lesions and ZTC that the establishment failed to address. When the FSMA identifies ZTC, follows official work instructions and requests immediate corrective action. However, his finding is not considered by DAFF as a deviation from the CCP for ZTC. As such, the only record made of the occurrence is a brief notation made by the FSMA's on the official inspection record without indicating that the occurrence was a HACCP regulatory non-compliance. In conclusion, the current regulatory approach being implemented by DAFF does not ensure adequately that this establishment meets U.S. requirements related to HACCP.

61. NAME OF AUDITOR

Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Lobethal Australia Pty., Ltd. Lot 41, Ridge Road Lobethal, South Australia 5241 Australia	2. AUDIT DATE August 1, 2013	3. ESTABLISHMENT NO. Australia 866	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Slaughter Establishment No. 866, Lobethal Australia Pty., Ltd.

Products from this establishment were involved in multiple port of entry (POE) violations related to zero tolerance contamination (ZTC). The establishment has developed a corrective action plan that includes modifying the kill floor to allow better flow of carcasses, minimizing cross contamination and relocating steps in the process to minimize digestive tract content spillage.

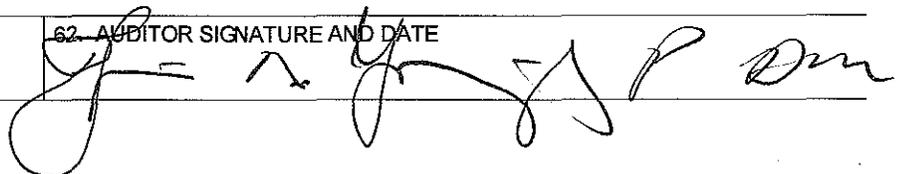
18. At this establishment, there are also three approaches in place used by plant management and government officials to assess carcasses to ensure that they comply with regulatory requirement for ZT controls. The establishment has a critical control point (CCP) in its HACCP plan that is designed to ensure that only carcasses that are free of ZTC leave the slaughter room. The establishment also conducts meat hygiene assessment (MHA) of the carcasses held in the holding coolers. In these two approaches the establishment documents the results of the assessments and institutes corrective actions when carcasses with ZTC are identified. Additionally, Department of Agriculture, Fisheries and Forestry in-plant officials (DAFF) verify the monitoring of the CCP by sampling carcasses in the slaughter floor and conduct MHA in the holding chillers. In those two approaches, DAFF verify the adequacy of corrective actions implemented by the establishment when carcasses with ZTC are identified by either the establishment or government verifiers.

The third approach involves the DAFF-food safety meat assessor (FSMA) stationed at the end of the evisceration line, past the company carcass inspectors, trimmers and the CCP monitoring station in the slaughter room. This government official is responsible for conducting final post mortem inspection of carcasses by identifying pathological lesions and ZTC that the establishment failed to address. When the FSMA identifies ZTC, follows official work instructions and requests immediate corrective action. However, his finding is not considered by DAFF as a deviation from the CCP for ZTC. As such, the only record made of the occurrence is a brief notation made by the FSMA's on the official inspection record without indicating that the occurrence was a HACCP regulatory non-compliance. In conclusion, the current regulatory approach being implemented by DAFF does not ensure adequately that this establishment meets U.S. requirements related to HACCP.

22. A review of records for the last six months of production showed that the establishment documents all corrective actions and makes them available for review by DAFF. However, the root cause analysis for the ZTC deviations was recorded as a failure on the part of personnel assigned to conduct post-mortem inspection carcasses, rather than the actual inadequate dressing practice that caused the problem. DAFF had not critically assessed the entries made in the corrective actions records kept by the company.

61. NAME OF AUDITOR  
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

<b>1. ESTABLISHMENT NAME AND LOCATION</b> Murray Bridge Pty., Ltd. Lot 10, Lagoon Road Murray Bridge, South Australia 5253	<b>2. AUDIT DATE</b> July 31, 2013	<b>3. ESTABLISHMENT NO.</b> Australia 533	<b>4. NAME OF COUNTRY</b> Australia
<b>5. NAME OF AUDITOR(S)</b> Francisco Gonzalez, DVM		<b>6. TYPE OF AUDIT</b> <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

<b>Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements</b>	Audit Results	<b>Part D - Continued Economic Sampling</b>	Audit Results
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8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

## Slaughter Establishment 533 T&amp;R Murray Bridge

Products from this Australian establishment were involved in port of entry violations that included positive for *E. coli* O157:H7 and zero tolerance contamination (ZTC). The establishment developed a corrective action plan and has modified the kill floor to allow better flow of carcasses and minimize cross contamination.

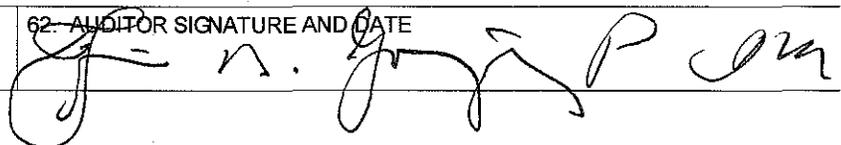
18. At this establishment, there are three approaches in place used by plant management and government officials to assess carcasses to ensure that they comply with regulatory requirement for ZT controls. The establishment has a critical control point (CCP) in its HACCP plan that is designed to ensure that only carcasses that are free of ZTC leave the slaughter room. The establishment also conducts meat hygiene assessment (MHA) of the carcasses held in the holding coolers. In these two approaches, the establishment documents the results of the assessments and institutes corrective actions when carcasses with ZTC are identified. Additionally, Department of Agriculture, Fisheries and Forestry in-plant officials (DAFF) verify the monitoring of the CCP by sampling carcasses in the slaughter floor and conduct MHA in the holding chillers. In those two approaches, DAFF verify the adequacy of corrective actions implemented by the establishment when carcasses with ZTC are identified by either the establishment or government verifiers.

The third approach involves the DAFF-food safety meat assessor (FSMA) stationed at the end of the evisceration line, past the company carcass inspectors, trimmers and the CCP monitoring station in the slaughter room. This government official is responsible for conducting final post mortem inspection of carcasses by identifying pathological lesions and ZTC that the establishment failed to address. When the FSMA identifies ZTC, follows official work instructions and requests immediate corrective action. However, his finding is not considered by DAFF as a deviation from the CCP for ZTC. As such, the only record made of the occurrence is a brief notation made by the FSMA's on the official inspection record without indicating that the occurrence was a HACCP regulatory non-compliance. In conclusion, the current regulatory approach being implemented by DAFF does not ensure adequately that this establishment meets U.S. requirements related to HACCP.

61. NAME OF AUDITOR

Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE



**APPENDIX B: Australia's Response to Draft Final Audit Report**



**Australian Government**  
**Department of Agriculture**

Dr Shaukat H Syed  
Director  
International Audit Staff  
Office of Investigation, Enforcement and Audit  
Food Safety and Inspection Service  
1400 Independence Ave, S.W.  
Washington D.C. 20250  
UNITED STATES OF AMERICA

Dear Dr Syed

Thank you for your letter dated 8 July 2014 in which you provided the Food Safety and Inspection Service (FSIS) Draft Final Report of the audit conducted from 29 July to 21 August 2013 on the Australian Export Meat Inspection System (AEMIS).

The Department of Agriculture (the department) appreciates FSIS' effort in conducting the audit and in providing comprehensive feedback to the department in the Draft Final Report.

The department acknowledges the overall finding that AEMIS meets the core criteria for all six equivalence components, and that AEMIS continues to maintain its equivalence with the United States system.

The department has undertaken a thorough assessment of the specific findings in the Draft Final Report. A response to each of the findings is provided at Attachment 1. We trust that the enclosed response, including the proposal to undertake further work in a number of areas, adequately addresses the findings in the Draft Final Audit Report.

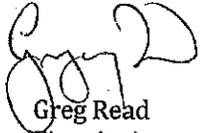
In addition to the response provided at Attachment 1, several related issues were discussed in my meeting with your FSIS colleagues in Washington D.C. on 8 August 2014. One issue raised was the continued port-of-entry detection for Australian meat imports. Data provided at Attachment 2 supports improvement in performance in these areas in 2014 compared to 2012 and 2013.

A further issue discussed at the meeting was audit report formats and whether there was a format both FSIS and the department would find acceptable and advantageous. As requested, we have included a suggested template at Attachment 3 for FSIS' consideration. This format may provide for a clearer description of findings for future audits.

Finally, we note the recent informal advice received through the Australian Embassy in Washington D.C. that the next audit of AEMIS, initially planned for 8 to 29 September 2014, has been postponed until December 2014. We would appreciate formal advice from FSIS of the revised audit dates in due course.

I look forward to your feedback on our response to the 2013 audit. Please do not hesitate to contact me if you require further information.

Yours sincerely



Greg Read  
First Assistant Secretary  
Exports Division

27 August 2014

**Attachments:**

1. Response to Draft Final Audit Report
2. Australian Meat Exports to the United States: Port-of-Entry Rejections 2011 – 2014
3. Proposed template – Draft Final Audit Report

## US 2013 Audit

## Response to Draft Final Audit Report

## General comments

The Department of Agriculture (the department) appreciates the assessment by the Food Safety and Inspection Service that Australia's meat inspection system meets the core criteria for all six equivalence components, and that overall, the system continues to maintain its equivalence with the United States system.

## Specific comments

#	Ref.	Issue	FSIS Finding	Department of Agriculture initial comments
<b>Component one: Government oversight</b>				
1	P7	MHA	MHA data does not include findings related to carcass contamination routinely identified by the FSMA that conducts carcass-by-carcass verification at the end of the line.	<p>Meat Hygiene Assessment (MHA) was introduced in 1996 at all Australian export registered slaughtering establishments. The application of MHA was expanded in 1997 to include boning, cold storage and sanitation operations. MHA was significantly revised in 2002. The implementation of MHA was and continues to be integral to the implementation of HACCP-based Quality Assurance programs.</p> <p>MHA is a process and product monitoring system. Process monitoring assesses the efficiency of sanitation and hygiene programs. Product monitoring assesses the success of the company process control to limit the level of macroscopic-contamination on carcasses, offal and carton meat. Product monitoring involves random sampling and detailed visual examination at product inspection stations. Sampling rates are</p>

#	Ref.	Issue	FSIS Finding	Department of Agriculture initial comments
				<p>based on production levels and on-going performance. Monitoring is conducted by establishment personnel and off-line government officials. The monitoring conducted by government officials is a verification of the performance of the establishment monitoring and is conducted independently. To ensure the outputs of this verification can be used to make valid comparisons to the outputs of establishment monitoring, off-line government officials are required to utilise the same product monitoring methods and product inspection stations utilised by the establishment.</p> <p>The Australia Export Meat Inspection System (AEMIS) was introduced in 2011. A key component of AEMIS is the verification of authorised officers performing post mortem inspection (PMV). Where post mortem inspection of carcasses is performed by Australian Government Authorised Officers, the PMV system also includes carcass by carcass assessment of every carcass processed and is performed by a Food Safety Meat Assessor (FSMA) at the end of the slaughter line. The primary purpose of carcass by carcass assessment is to verify carcasses are free from food safety pathology and obvious contamination.</p> <p>The FSMA carcass by carcass assessment system operates independently from the MHA system. The outputs of the carcass by carcass assessment are not intended to be directly included in the outputs of the MHA system due to the different purposes of these systems and the different inspection and</p>

#	Ref.	Issue	FSIS Finding	Department of Agriculture initial comments
				<p>monitoring methodologies.</p> <p>In light of the concerns raised in the FSIS draft audit report the department will review the relationship between the outputs of MHA and post mortem inspection verification including the carcass by carcass assessment to determine if changes to MHA are required.</p> <p>It is anticipated that this process will be completed by the end of November 2014.</p>
2	P8, 9, 10	ZT CCP	<p>The CCA has omitted from the instructions to in-plant personnel, provisions that would instruct inspectors to document deviations from the CCP for ZT contamination as evidence of inadequate implementation of establishments' HACCP plans. Presently in-plant inspection personnel document such non-compliances as carcass contamination incidents. FSIS reviewed records maintained by in-plant officials at several establishments and observed that entries reporting results of daily ZT-CCP verification do not relate findings of ZT non-compliance to deviations from the CCP. In a similar manner, in-plant government officials do not document FSIS' reported POE-related ZT violations as events related to inadequacies in the establishments' implementation of their HACCP</p>	<p>In response to the finding in the draft FSIS report the department has reviewed the current departmental instructional material for the verification of the critical control point for zero tolerance defects on carcasses and for the implementation of HACCP plans. The review has found the current instructional material is focused on the procedures for undertaking verification activities and the actions required when individual verification activities detect CCP failures. The review has concluded that the instructional material does not provide adequate instruction to assist on-plant government officials in their consideration of repetitive findings of zero tolerance defects and how these relate to potential failure of the establishment to effectively implement its HACCP plan. The department agrees with the FSIS finding detailed in the draft audit report.</p> <p>The department is in the process of modifying instructional</p>

#	Ref.	Issue	FSIS Finding	Department of Agriculture initial comments
			<p>programs. These procedural inconsistencies in government oversight prevent establishments from accurately assessing their ability to implement their HACCP programs and could cause the CCA and establishments to inaccurately conclude that the HACCP plans are working as intended.</p> <p>The review of records conducted by FSIS showed that in-plant officials identify non-compliances, take official control actions, document all actions, and require corrective actions. However, as discussed in the HACCP component, corrective actions do not include adequate preventative measures.</p> <p>FSIS reviewed post-mortem inspection records and noted that the end-of-chain (EOC) FSMAs regularly identify ZT contamination on carcasses and document such occurrences, but CCA officials do not use that data to evaluate the adequacy of implementation of establishments' HACCP plans, but rather, as an indicator of repetitive CCP for ZT deviations being identified by EOC FSMAs as events that directly relate to inadequate implementation of the slaughter HACCP plan. Correspondingly, regulatory actions needed to correct such deficiencies are</p>	<p>material to address this finding. The department is using FSIS PHIS Directive 6420.2 to guide this process, especially Chapter V Enforcement. Upon completion of modification of the instructional material the department will undertake training of on-plant government officers and Area Technical Managers to ensure they understand how these processes are required to be implemented and documented. Effectiveness of this training will be verified during audits of establishments by Area Technical Managers and Field Operations Managers. It is anticipated that this process will be completed by the end of November 2014.</p>

#	Ref.	Issue	FSIS Finding	Department of Agriculture initial comments
			<p>not being implemented.</p> <p>Corrective actions implemented by the CCA must prevent recurrence of the findings reported for this component of the Australia meat inspection system.</p>	
<b>Component two: Statutory authority and food safety regulations</b>				
3	P12	Maintenance of facilities	<p>Documents reviewed by FSIS during the audit indicate that operators of the establishments and government officials interact to ensure that non-compliances related to the maintenance of the facilities are identified and addressed to comply with the regulations of the program. However, as further described in the Sanitation component of this report, in-plant officials need to assess in a more critical manner the implementation of sanitation programs to identify and require abatement of potential sources of production contamination.</p>	<p>The department accepts the sanitation defects summarised in the FSIS draft report are evidence of inadequate implementation of maintenance and sanitation programs. The department appreciates the comments made by the auditor in the report that these defects were addressed by prompt corrective measures and that documentation reviewed by the auditor indicated that operators of the establishment and on-plant government officials interact to ensure that non-compliances related to maintenance are identified and addressed.</p> <p>However, the draft audit report provided to the department did not include the Individual Foreign Establishment Audit Checklist referenced as Appendix A. The department requests that these checklists are provided to facilitate our response to the draft audit report findings.</p> <p>The department can confirm that it is committed to ensuring all US listed establishments implement effective maintenance and sanitation programs that prevent product contamination. To ensure that all US listed establishments continue to meet these</p>

#	Ref.	Issue	FSIS Finding	Department of Agriculture initial comments
				<p>requirements the department will require on-plant government officers at all US listed establishments to conduct a targeted audit on the establishment sanitation and maintenance programs. The defects summarised in the FSIS reports will be used as examples of the type of defects that need to be more effectively managed. Where audits identify that establishment maintenance and sanitation programs are inadequate, establishments will be required to implement corrective and preventive actions. These audits and actions will be verified by Area Technical Manager and Field Operation Manager audits. This action will be completed by the end of November 2014.</p>
<b>Component three: Sanitation</b>				
4	P14	Examples of sanitation non-compliance and sanitation programs	<p>At three of the six audited establishments there were sanitary concerns that had not been identified by the OPV:</p> <ul style="list-style-type: none"> <li>• At one establishment, numerous conveyor belts had become frayed. Standing surfaces had deteriorated, which created surfaces difficult to clean and sanitise.</li> <li>• At another establishment, there was clutter in the packing supplies storage room, and trash had accumulated in several areas, close to product contact surfaces.</li> <li>• At a third establishment, while observing dressing of sheep, an automatic hide</li> </ul>	See response to Finding #3.

#	Ref.	Issue	FSIS Finding	Department of Agriculture initial comments
			<p data-bbox="632 354 1108 444">puller was seen causing contaminated hides to come into contact with skinned surfaces of other uneviscerated carcasses.</p> <p data-bbox="541 488 1100 781">These findings, although addressed by prompt corrective measures by the establishments, indicate establishments need to monitor better sanitary conditions of their equipment and facilities. In addition, in-plant officials need to assess in a more critical manner the implementation of sanitation programs to identify and require abatement of potential sources of product contamination.</p> <p data-bbox="541 821 1121 912">Implementation of adequate corrective actions to address these findings will improve the performance of this component.</p>	
<b>Component four: HACCP systems</b>				
5	P15	CCP monitoring frequency	<p data-bbox="541 954 1121 1279">The six establishments conduct carcass examination at the CCP for ZT based on monitoring frequencies provided in govt guidelines. With this approach, establishments are allowed to use a reduced monitoring frequency recommended for establishments in good status, i.e. examining 32-45 carcasses per shift. However, that monitoring frequency does not adequately detect deviations from the critical limit. This practice results in numerous</p>	<p data-bbox="1144 954 1898 1279">The department believes that there may have been a misunderstanding in relation to CCP1 (absence of feces/ingesta/milk on carcasses) monitoring frequency. MHA allows for a variable frequency for carcass defect checks on a "reduced - normal -intensified" basis. Many establishments have utilised the MHA carcass defect checks for HACCP purposes, however, we are not aware of any establishments that use the "reduced" frequency for HACCP, instead using only the "normal" or "intensified". As a result of the FSIS audit outcome, the department will require industry to review the</p>

#	Ref.	Issue	FSIS Finding	Department of Agriculture initial comments
			deviations from the ZT critical limit that are detected by the EOC FSMAs, rather than being detected at the CCP monitoring station, as the establishments' HACCP plans require.	justification of the monitoring frequency for CCP1 with an emphasis on risk-based decision making rather than the adoption of MHA frequencies. This determination should be a fixed number for the class of livestock being slaughtered at their plant.
6	P16	Prevention of ZT CCP deviations	Establishments respond to numerous ZT CCP deviations reported by EOC FSMAs by implementing pertinent corrective actions in accordance with their HACCP plan to ensure the CCP will be under control after the corrective action is taken. However, measures to prevent recurrence of deviations are either not instituted or inadequately implemented by establishments.	See response to Finding #2.
7	P16	Cause of ZT CCP deviations	Establishments' records show as the root cause of ZT CCP deviations, inadequate performance of AAOs' post-mortem inspection duties, rather than shortcomings in the dressing process that cause the contamination events. This inadequate assessment of the actual cause of the reported ZT CCP deviations prevents the establishments from instituting adequate corrective actions.	The department would like to clarify that company Quality Assurance staff are accountable for ZT CCP deviations and for the response to these findings, rather than the AAO. AAOs are responsible for the detection of pathological hazards (CCPs are not set for pathology).
8	P16	Re-assessment of HACCP under the new inspection	The six establishments operate under a newly introduced system of post-mortem inspection that affects the slaughter process. Following introduction of such changes, the establishments did not reassess their HACCP plans, even when FSMAs repetitive ZT CCP deviations bring into	See response to Finding #2.  Also, the department believes that the change in the system did not require HACCP reassessment as the meat inspectors are still trained to the same level and the interventions relating to CCPs are the same under the new system. The new system

**Attachment 1**

#	Ref.	Issue	FSIS Finding	Department of Agriculture initial comments
		system	question the adequacy of implementation of their slaughter HACCP plans.	merely changes who engages the meat inspectors and does not impact on the effectiveness of the slaughter HACCP plans.
9	P16	Verification of corrective actions following POE violations	The FSIS auditor verified that establishments and govt offices have responded to 14 POE violations reported by FSIS from Oct 2011 to Sept 2013, including ten instances of ZT deviations related to faecal matter and ingesta on meat products. The CCA and the establishments involved have responded to FSIS reports by conducting investigations, redesigning their kill floors to prevent carcass contamination, and assessing the adequacy of the establishments' HACCP plans. However, the CCA verification activities were incomplete, as made evident by the findings described above.	See response to Finding #3.

**Australian Meat Exports to the United States:  
Port-of-Entry Rejections 2011 – 2014<sup>1</sup>**

**Macroscopic contamination**

Year	OIE Case Number	Date Notified	Est. Number	Product	Detection
2014					
	2014-AU-90-01	8/07/2014	90	bone-in-lamb	off condition
	2014-AU-394-04	19/03/2014	394	bone-in lamb	faeces/ingesta
	2014-AU-394-02, 03	6/03/2014	394	boneless/bone-in lamb	faeces/ingesta
	2014-AU-394-01	27/02/2014	394	bone-in lamb	ingesta
2013					
	2013-AU-234-01	12/12/2013	234	boneless beef trim	abscesses
	2013-AU-180-01	12/12/2013	180	boneless beef trim	ingesta
	2013-AU-1614-01	26/11/2013	1614	bone-in lamb	ingesta
	2013-AU-866-01	10/05/2013	866	bone-in goat	faeces
	2013-AU-2309-03-05	2/05/2013	2309	bone-in mutton	faeces
	2013-AU-2309-02	2/05/2013	2309	boneless mutton	faeces
	2013-AU-300-01-02	5/03/2013	300	raw intact veal cuts	metal
2012					
	2013-AU-2309-01	28/11/2012	2309	raw intact mutton	ingesta
	2013-AU-1912-01	28/11/2012	1912	boneless beef trim	faeces
	2013-AU-533-01	15/11/2012	533	raw intact lamb	ingesta
	2013-AU-612-01-02	6/11/2012	612	raw intact goat	ingesta
	2012-AU-866-05	6/08/2012	866	bone-in lamb	faeces
	2012-AU-206-01	8/06/2012	206	bone-in goat	faeces
	2012-AU-486-01	5/06/2012	486	boneless beef trim	faeces/ingesta
	2012-AU-612-01	1/02/2012	612	mutton	faeces/ingesta
	2012-AU-866-04	1/02/2012	866	lamb	faeces/ingesta
	2012-AU-866-01-03	24/01/2012	866	mutton	faeces/ingesta
2011					
	2012-AU-344-01-04	15/11/2011	344	goat cuts	faeces/ingesta
	2011-AU-344-01	30/08/2011	344	goat sides	ingesta
	2011-AU-008-01	28/04/2011	8	mutton	faeces

<sup>1</sup> Data current to 15 August 2014

**Shiga toxin-producing *Escherichia coli***

Year	OIE Case Number	Date Notified	Est. Number	Product	Detection
2014	N/A				
2013					
	2013-AU-239-02	15/10/2013	239	beef trim	O26
	2013-AU-239-01	2/10/2013	239	beef trim	O157:H7
	2013-AU-235-01	5/03/2013	235	beef trim	O157:H7
2012					
	2012-AU-224-03	19/06/2012	224	beef trim	O157:H7
	2012-AU-224-02	6/06/2012	224	beef trim	O157:H7
	2012-AU-0239-03	30/01/2012	239	beef trim	O157:H7
	2012-AU-0239-02	19/01/2012	239	beef trim	O157:H7
	2012-AU-0157-01	19/01/2012	157	beef trim	O157:H7
2011					
	2011-AU-533-01	3/05/2011	533	beef trim	O157:H7

